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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/756,219

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Donald R. Sandell

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APPLIED BIOSYSTEMS
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EXAMINER

BEISNER, WILLIAM H

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/756,219	Applicant(s) SANDELL, DONALD R.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52,54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52,54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 52 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850).

The reference of Rochte et al. discloses a method for performing an automated chemical analysis on samples positioned in a sample well tray (24) in an incubation device (400). The method includes providing a translatable sample block assembly (402); moving the sample block assembly (402) from a first position permitting placement of the sample well tray onto the incubation device (400) to a second position permitting incubation within the incubating device (400) (See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); positioning the sample well tray (24) onto the sample block assembly (402) to engage the

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sample well tray to the sample block assembly (See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); maintaining the upper portion of the incubation device substantially stationary (See Figures 3 and 5 and See column 9, line 65, to column 10, line 21; and column 13, line 59, to column 14, line 3); and incubating the samples in the tray to perform the desired chemical reaction. Note the sample well tray (24) is configured so that it can horizontally translate into and out of the thermal cycling device. Specifically, the sample well tray (24) horizontally translates into and out of the thermal cycling device (400) along rails (22) and racks (26) (See column 3, lines 38-50; column 4, lines 34-64; and Figure 5).

Claim 52 differs by reciting that the sample includes nucleic acid and the chemical reaction performed is nucleic acid amplification by thermally cycling the sample mixture.

The reference of Wheatcroft discloses that it is known in the art to perform nucleic acid amplifications in an automated chemical analysis device the includes incubation stations (See page 2, lines 10-30; Figure 1; and page 7, line 36, to page 9, line 21).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to perform nucleic acid amplifications in the system of the primary reference of Rochte et al. for the known and expected result of providing an art recognized means for automating an analytical chemical reaction process. When modifying the reference of Rochte et al. as discussed above, the sample block assembly (402) control would be cycled to provide the thermal cycling required to perform nucleic acid amplifications.

With respect to claim 55, both the references of Rochte et al. and Wheatcroft disclose that operation of the devices is automated (See the abstract of Rochte et al. and column 7, lines 31-36, of Wheatcroft).

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4. Claims 52, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) taken further in view of Woudenberg et al.(US 5,928,907).

The combination of the references of Rochte et al. and Wheatcroft has been discussed above.

Claims 52, 54 and 55 differ by requiring that the second position allows alignment of the sample well tray with an substantially stationary optical detection system and detecting the amplification during the thermal cycling.

The reference of Woudenberg et al. discloses that it is known in the art to configure a cover or platen (14) that is heated within an integrated optical detection system (10, 8, 6, 4, 2) (See Figure 1) such that the contents of the sample wells can be detected during the thermal cycling process.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the incubation station of the modified primary with an optical detection system as suggested by the reference of Woudenberg et al. for the known and expected result of providing a means recognized in the art for providing real-time fluorescence detection of the thermal cycling reaction within the sample wells.

Response to Arguments

5. With respect to the rejection of Claim 52 under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) and Claims 52 and 54

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under 35 U.S.C. 103(a) as being unpatentable over Rochte et al.(US 3,545,690) in view of Wheatcroft (CA 2,255,850) taken further in view of Woudenberg et al.(US 5,928,907), Applicant argues that the rejections of the claims are improper for the following reasons.

i) *The reference of Rochte et al. incubates samples rather than thermal cycle samples which is a completely different process* (See page 3 of the response dated 6/4/2008).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, it is the combination of the references that suggest using the system of the primary reference for thermal cycling samples.

ii) *The entirety of the analyzer taught by Rochte has stations that are not contained in a housing, so that the aluminum block of Rochte is not within the device of Rochte* (See page 3 of the response filed 6/4/2008).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an environmentally isolated housing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, the Examiner is of the position that combined teachings of the references meet the instant claim language. That is, the incubating or thermal cycling zone in the system of the modified Rochte is

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considered a thermal cycling device. The sample tray and samples therein are provided external to this station or zone within the system. As a result, the modified reference of Rochte meets the instant claim language. It is noted that the instant claims do not require that the thermal cyclers and/or the sample block are environmentally isolated and/or held within a housing as argued by applicants.

iii) *The cited references fail to provide the necessary motivation, which motivation cannot be found either in the references alone, or in combination* (See page 3 of the response dated 6/4/2008).

In response, as indicated by the Supreme Court, *KSR* forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See *KSR International Co. v. Teleflex Inc.*, 550 U.S.----, 82 USPQ2d 1385, 1397 (2007).

Furthermore, the *KSR* decision makes clear that the teaching, suggestion, or motivation (TSM) test is not the only rationale that may be relied upon to support a conclusion of obviousness. In this case, the Examiner has articulated the following: i) a finding that the prior art contained a "base" method (Rochte et al.) upon which the claimed invention can be seen as an "improvement"; ii) a finding that the prior art (Wheatcroft) contained a known technique (performing nucleic acid amplification within an automated chemical analyzer) that is applicable to the base method (Rochte et al.); and iii) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results (automation of a nucleic acid amplification process) and resulted in an improved system (use of the system of Rochte et al. to perform nucleic acid amplification). As a result, the Examiner is of the

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position that a *prima facie* case of obviousness has been established as required under 35 USC 103(a).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB